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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,074	09/28/2000	Philip Henry Coelho	30111-pa	4198

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,074

Applicant(s)

COELHO ET AL.

Examiner

Kaj Olsen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11-13, 19-22, 28-32 and 45-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 11-13, 28-32 and 45-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 and 56-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-5, 11-13, 28-32, and 45-54 remain non-elected and withdrawn from further consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 63-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 63-67 all add limitations drawn to the use of a "thermosetting material". There is no discussion of the use of a thermosetting material in the originally filed disclosure.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 58, 59, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The preamble of claims 19 and 60 states the invention is drawn to a method of forming a bag, but claims 58, 59, and 62 appear to be drawn to a method of using the bag making it unclear

what class of statutory invention the applicant is claiming (a process of making or a process of use?).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Medwed.

9. Medwed discloses a forming a container (i.e. bag) which comprises forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface, and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface (fig. 2 as an example). A sheet is placed over said mold and is caused to conform to the mold and retains having the configuration of the mold (fig. 1 and 4). The conformed sheet is removed from the mold and the first sheet is closed with another sheet parallel to the planar surface (fig. 1 again). It would appear that the “thermoplastic” utilized by Medwed would qualify as a “thermosetting material” giving the claim language its broadest reasonable interpretation. Moreover, the container constructed by Medwed would also read on the claim language drawn to the resistance to brittleness and deformation giving those claim terms their broadest reasonable interpretation.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 19-22, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider (USP 4,591,357) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

13. Sneider discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1 and 2). However, Sneider does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck

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for the formation of the container of Sneider because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Sneider discloses a plurality of portals (fig. 1 and 2) and the teaching of Sneider in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. The container of Sneider is disclosed as utilized for medicines requiring dilution and medicines can include thermolabile or biological substances. Portal 16 would be closed during mixing.

14. Claims 19-22, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al (USP 5,108,387) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

15. Falk discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1a). However, Sneider does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the

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formation of the container of Falk because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Falk discloses a plurality of portals (5, 6) of which 5 is sealed after filling (col. 4, lines 10-28) and the teaching of Falk in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. Falk teaches utilizing the container for dialysis concentrates which can include thermolabile or biological substances such as enzymes or antibodies.

16. Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed.

17. Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed.

18. The references above set forth all the limitations of these new claims (see rejection above for discussion of limitations not covered here), but none of Sneider, Falk, or Heck explicitly set forth the use of a thermosetting material for the method of construction. Rake sets forth in an alternate medical container that it is conventional in the art to utilize materials such as thermosetting materials for the construction of medical containers (col. 10, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time the invention was being

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made to utilize the teaching of Rake for the method of either Sneider or Falk in view of the Heck, because thermosetting materials are readily available and have been identified as suitable materials for medical container construction. The containers constructed by the above references would also read on the claim language drawn to the resistance to brittleness and deformation giving those claim terms their broadest reasonable interpretation.

Response to Arguments

19. Applicant's arguments filed 5-29-2002 have been fully considered but they are not persuasive. With respect to the rejections under 35 U.S.C. 112 concerning the appropriate statutory class of invention, applicant urges that they should not be penalized because the invention does not fall neatly into a statutory invention class. However, it is well understood that claim interpretation (both in prosecution and in enforcement) depends heavily on the statutory class of invention. For example, process steps in a product claim are treated differently than a claim drawn to a process of making a product. The failure to set forth the invention such that the statutory type of invention is clear renders the claims indefinite, because the scope of the claims is not clear. In particular, freezing a bag after it has been formed does not appear to be a process of making a bag (the examiner is using claim 58 as an example). Rather it would appear to be drawn to a process of using the product formed by the process of making. If claim 58 is drawn to a process of using a product made from a process of making the product, then what structural elements of the product are clearly being set forth to be utilized by the process of using? Hence the failure to clearly define the invention renders these claims indefinite.

20. In addition, the examiner questions whether the applicant's instant invention cannot fall neatly into the types of statutory invention set forth by the office. Using claim 58 as an example again, how can freezing a bag after it has been formed and filled not fall neatly in the statutory definitions of an invention? If the claim is drawn to a process of using a product, applicant could claim a process of using the product where the product is defined in terms of the process of making the product. In summary, the examiner does not believe that the invention itself fails to fall neatly in the statutory types of invention, rather *the claims as presented* fail to fall within the statutory types of invention.

21. With respect to the rejections under 35 U.S.C. 102, applicant urges that Medwed is not drawn to a medical bag. The examiner agrees. However, the claim rejected with Medwed (both in this office action and in the previous office action) is merely drawn to a method of forming a bag. Applicant also urges that the bags produced by the method of the instant invention are not rigid like the containers of Medwed. This may be the case, but the instant invention is not being claimed in a manner that reads away from the teaching of Medwed.

22. With respect to the rejections under 35 U.S.C. 103, applicant first urges the examiner's use of evidentiary references with the preface "with or without" obscures the issues and burdens the record. However, the examiner is of the opinion that his use of the "with or without" has been clearly established on the record. To clarify, the examiner believes there is sufficient motivation to combine the teaching Heck with Sneider or Falk because the process of forming containers by the defined invention would appear to be conventional in the art. However, there is additional motivation to utilize the particular technique of vacuum molding suggested by Heck because the evidentiary art recognizes additional advantages of the use of vacuum molding. The

evidentiary references also clearly show the flashings that are present. The use of the “with or without” is equivalent to the widespread office use of alternative rejections utilized to strengthen the office’s rejection of the claims.

23. With respect to Sneider, applicant urges that there is no evidence that Sneider retains its shape. However, Sneider specifies in the discussion of fig. 1 and 2 that the device is of “molded flexible plastic and having a selected shape” (col. 3, lines 52 and 53). The selected shape shown in figure 2 reads on the claimed invention. Moreover figure 2 shows the device possessing the selected shape even though it appears to be only partially filled with fluid clearly showing that container retaining its conformation. Applicant also argues that there is no evidence that the container would not rupture under the extreme forces of non-ambient conditions. However, it is the examiner’s understanding that the specified shape of the instant invention’s shape is what gives rise to its resistance to the forces engendered under freezing and the utilized prior art also possesses said claimed shape. With respect to the applicant’s argument that Sneider does not set forth the specified peripheral flashing, the examiner points out elements 18, 19, and 12 of fig. 1. In addition, peripheral flashings would result from the use of vacuum molded halves (see Heck with or without Nathoo or Medwed).

24. With respect to Heck, applicant argues that a general statement about different formation techniques does not provide sufficient motivation to combine the two references (presumably Heck and Sneider) with each other. However, all of the formation techniques discussed by Heck are old in the art, and none of them have any particular specificity to the container constructed by Heck. One possessing ordinary skill in the art would have looked to conventional techniques for forming medical containers such as that of Sneider or Falk.

25. Applicant alleges that Nathoo is non-analogous art. It is unclear what applicant is referring to. Is the art considered non-analogous in the sense that it is not drawn to the construction of medical containers? Whether or not Nathoo is drawn to medical containers would appear to be irrelevant in view of how the reference is utilized in its evidentiary capacity. The use of vacuum molding was already demonstrated by Heck. Nathoo merely shows that the structure formed by the vacuum molding of Heck possesses the specified features (i.e. peripheral flashings) and has advantages over other prior art techniques (i.e. less prone to ripping or tearing). In other words, Nathoo demonstrates what is inherent concerning a process already specified by the analogous art of Heck. The kinds of structures Nathoo is ultimately drawn to would appear to be irrelevant for what the reference has been utilized for.

26. Applicant urges with respect to Falk that the container may not be able to withstand the phase change forces because of its collapsible nature. However, it would appear to the examiner that its collapsible nature, in addition to the fact that it has the specified shape defined by the claims, would precisely make it able to withstand the phase change forces. It already responds to the forces present when the container is being emptied and filled without changing its shape (fig. 1a and the associated discussion).

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 8:30 AM-6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for non-after final communications is (703) 872-9310 and the fax number form after-final communications is (703) 872-9311.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen
Patent Examiner
AU 1744
September 9, 2002



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